

The U.S. Patent and Trademark Office (USPTO) issued the above-referenced U.S. Patent No. 7,375,354 (the '354 patent) on May 20, 2008, with a patent term adjustment (PTA) of 990 days. Subsequent to May 20, 2008, on September 30, 2008, U.S. District Court for the District of Columbia ruled in *Wyeth v. Dudas*, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063 (D.D.C. Sept. 30, 2008) that the USPTO had misinterpreted 35 U.S.C. § 154(b)(1)(A) or § 154(b)(1)(B), resulting in improper PTA calculations. Specifically, the District Court's decision addressed the USPTO's method of determining PTA based on patent term adjustments that accrue under either 35 U.S.C. § 154(b)(1)(A) or § 154(b)(1)(B). The court ruled that patent term adjustments that occurred under 35 U.S.C. § 154(b)(1)(A) before the 3-year period under §

154(b)(1)(B) should be counted in addition to patent term adjustments that result from failure to issue a patent within three years under § 154(b)(1)(B) because, contrary to the USPTO's interpretation of the Statute, such patent term adjustments were not overlapping adjustments.

In light of these circumstances, Patentee respectfully requests waiver of time limit set forth in 37 C.F.R. § 1.705(d) to permit filing and consideration of the accompanying Application for Patent Term Adjustment - Post Grant, in which Patentee requests a change in the PTA based on determination in a manner consistent with the District Court's decision in *Wyeth*. Patentee notes that since the District Court's decision was not issued until September 30, 2008, Patentee was not able to file an Application for Patent Term Adjustment within the two month time period under 37 C.F.R. § 1.705(d), following the District Court's determination that resulted in Patentee's patent being eligible for additional PTA. Therefore, Patentee respectfully submits that waiver of the time limit is appropriate in order to provide Patentee with an opportunity to file the attached Application for Patent Term Adjustment.

Please charge to the required petition fee payment of \$400.00 to our Deposit Account 06-0916, as set forth in 37 C.F.R. § 1.17(f). If there are any additional extension of time or required fees due in connection with the filing of this Petition, please grant such extensions and charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 14, 2008

By: 

Matthew T. Nesbitt  
Reg. No. 57,734



1. The above-identified application was filed March 15, 2004, under 37 C.F.R. § 1.53(b) as a divisional application.
2. The first action on the merits issued by the U.S. Patent and Trademark Office was a Notice of Allowance, which was issued on January 30, 2008. This resulted in a USPTO delay of 660 days beyond the 14 months provided by 35 U.S.C. § 154(b)(1)(A).
3. Patentee timely paid the issue fee on April 21, 2008.
4. There were no delays attributable to the Patentee.
5. U.S. Patent No. 7,375,354 issued on May 20, 2008, resulting in an additional USPTO delay of 432 days under the three-year pendency rule provided by 35 U.S.C. § 154(b)(1)(B).

Under *Wyeth*, the period of patent term extension under 35 U.S.C. § 154(b)(1)(B) tolls three years after completion of the national stage application, i.e., three years from the March 15, 2004, filing date. Thus, the period of patent term extension under 35 U.S.C. § 154(b)(1)(B) tolled on March 15, 2007. Because the first USPTO delay occurred on May 15, 2005 (i.e., 14 months after the filing date), and lasted until March 15, 2007, *Wyeth* instructs that the initial USPTO delay of 660 days should be counted in addition to the subsequent 432-day USPTO delay under the three-year pendency rule. Thus, because there are no reductions in the term adjustment, the total adjustment based on USPTO delay is 1092 days. Thus, Patentee respectfully requests that the current patent term adjustment be reconsidered and changed from the current, incorrect term of 990 days to the correct term of 1092 days.

## **B. Terminal Disclaimer**

The above-identified application is not subject to a Terminal Disclaimer.

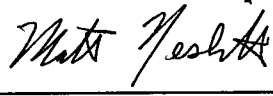
## II. Fee Payment

As required under 37 C.F.R. § 1.705(b)(1), Patentee requests that the appropriate fee payment of \$200.00 be charged to our Deposit Account 06-0916. If there are any extensions of time or other additional fees due in connection with the filing of this Application, please grant such extensions of time and charge such fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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